



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,857	12/28/2000	G. Patrick Stahly	13001US01	1453

7590 12/04/2002

Michael B. Harling  
McAndrews, Held & Malloy, Ltd.  
500 West Madison Street, 34th Floor  
Chicago, IL 60661

EXAMINER

GAKH, YELENA G

ART UNIT	PAPER NUMBER
----------	--------------

1743

DATE MAILED: 12/04/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/752,857

Applicant(s)

STAHLY ET AL.

Examiner

Yelena G. Gakh, Ph.D.

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. The Amendment filed on 10/07/02 is acknowledged. Claims 1-55 are pending in the application.

#### *Response to Amendment*

2. The pending claims stand rejected mainly on the same grounds as were established in the previous Office action.

#### *Specification*

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "Methods of generating and screening of different forms of polymorphs" or "Methods of screening compounds for possible polymorphic forms".

4. The specification is objected to as not containing "*a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention*" (35 U.S.C. 112, first paragraph). The invention is referred to a method of "searching for possible forms of a sample", which is a completely unclear expression. Which sample is meant here and why it should exist in different forms? It is not even clear, if the sample has anything to do with chemistry or biochemistry. What the forms of the sample are? Are these shapes? Are these different phases? The section "Field of Invention" should be written in a clear and definite language, which is not the case for the present specification. The term "searching" itself is an indefinite term, since it is not clear, what kind of method steps it may involve. Also, what is the difference between "searching" and "screening"? If "screening" is not a way of "searching", than what both of these terms mean in

Art Unit: 1743

the present application? The specification should be written in such precise and definite terms that it would be clear from the very beginning, what the subject matter of the invention is.

### *Double Patenting*

5. Claims 34 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). All steps of claim 34 are the same as the steps of claim 1, and the word “screening” is conventionally used in the fields of analytical chemistry and biochemistry in terms of “searching” for compounds with specific properties.

### *Claim Rejections - 35 USC § 112*

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 41 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a specific sample, i.e. the sample of a compound which may have potential biological activity, does not reasonably provide enablement for any other sample. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification does not enable anyone to provide “data indicative of biological activity or bioavailability” of e.g. synthetic resins or toxic chemicals.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1743

9. Claims 1-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, "a method of searching for possible forms of a sample". This language renders claims unclear and indefinite, as was discussed above.

Claims 1 and 34 recite "forms" of a sample, which is an indefinite term, since it is not clear, which characteristics of the sample it defines. Are these physical forms, chemical forms, mechanical forms, shapes, etc.? Such terminology renders the claims unclear and indefinite. Claims 1 and 34 further recite classification of said form, however, it is not clear, what type of classification is meant here.

The language of claims 26 and 27 stays unclear; see Response to the Applicants' Remarks.

Amended claim 53 contains un-clear and indefinite language: "wherein the analytical result is indicative of form". Which "form"? The "form" of what? Nothing in the claim indicates that the compound (not the sample!) can exist in different polymorphic forms. Therefore, it is absolutely unclear, which form is meant here.

Claim 54 remains completely unclear (see Response to the Applicants' Remarks).

### *Claim Rejections - 35 USC § 102*

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(1) shall have the effects for the purposes of their subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language."

Art Unit: 1743

11. **Claims 1-3, 6-9, 11, 13, 14, 20, 21, 34-37, 39, 40, 42, 43, 45 and 50-52** are rejected under 35 U.S.C. 102(e) as being anticipated by Hol et al. (US 6,267,935 B1).

Hol teaches a method for screening different crystalline and amorphous forms of biologically active macromolecules placing solutions in a plurality of receptacles and crystallizing them by different techniques, including evaporation of the solvent with following monitoring of the process by stereomicroscope and further by X-ray diffraction analysis. The conditions are varied to obtain crystal forms instead of amorphous forms for some of the compounds. "In the technique of capillary crystallization, layers of sample solution and crystallization solution can be deposited in a capillary 0.5-1.0 mm in diameter, either with an air space between the solutions or with a direct liquid--liquid interface. Crystallization occurs by vapor diffusion or liquid--liquid diffusion inside the capillary" (col. 10, lines 51-56).

12. **Claims 1, 2, 8, 9, 11, 13, 17, 18, 20, 34, 36, 39, 40, 42, 45, 48, and 49** are rejected under 35 U.S.C. 102(b) as being anticipated by Plaas-Link (US 5,009,861).

Plaas-Link discloses a method of determining crystal forms of samples using a crystallization apparatus to crystallize e.g. biologically active proteins from solutions inside a glass capillary so that "unhampered observation of the crystallization progress is made possible" (col. 4, lines 14-17) when "liquid is evaporated out of the capillary tubes" (col. 4, lines 20-22). The observation of the formation of crystals has an inherited step of classification them as crystals. A plurality of capillaries or cells is disclosed for crystallization of a plurality of protein samples.

13. **Claims 1-3, 8, 9-11, 13, 17, 18, 20, 21, 34-40, 42, 45, 48, and 49** are rejected under 35 U.S.C. 102(b) as being anticipated by Schuler et al. (US 4,295,857, IDS).

Schuler teaches a process for the crystalline precipitation of chromogenes within a capillary, i.e. determining crystalline forms of the samples. "The process involves first initiating a course of crystalline precipitation of the chromogen by initially and locally supersaturating the solution within the capillary, and thereafter evaporating the solvent at a rate and in an environment sufficient for further crystallization to proceed unimpeded by local supersaturation" (Abstract). In the Background of the Invention Schuler discloses preparation and observation of formation of several forms, crystalline, as well as amorphous, of several biologically active compounds, in capillaries by evaporating solvent with following spectroscopic analysis (columns

Art Unit: 1743

1 and 2). "It has been proposed to include such small amounts of substance in a solvent, fill a capillary with the resultant solution, and precipitate the substance by evaporating the solvent in the capillary". In the case of 4-aminophenazone, "this substance tends to deposit from a large number of solvents upon evaporation of the solvent not in crystalline form but as an amorphous oil. The oil obtained begins to solidify after a short period of time forming a yellow color, and a resinous hydrophobic layer is produced by which the capillary loses its absorption capacity. The yellow coloration of the substance expresses itself in a new band in the absorption spectrum and has a disturbing effect on photometric measurement due to the occurrence of high reagent blank values. If the conditions under which the solvent is evaporated are varied, for instance by applying a vacuum, it is, it is true, possible in individual cases to obtain a finely crystalline precipitation with good absorptivity" (col. 2, lines 15-33). In the Background of the Invention Schuler discusses preparation of a mixture of several components using capillaries (col. 1, lines 25-45).

14. **Claims 1, 2, 8, 9, 11, 13, 16-18, 20, 22, 23** are rejected under 35 U.S.C. 102(b) as being anticipated by JP 06095190.

JP 06095190 discloses growing an organic single crystal in a capillary by heating inserted capillary in the furnace, rotating it while evaporating the solvent and detecting and discriminating the organic single crystal by Raman diffusion spectroscopy.

### ***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1743

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. **Claims 4, 5, and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Schuler.

Schuler does not particularly disclose disposing the compounds in different types of receptacles, including non-capillary or subjecting at least two different samples to different conditions during solidifying step. However, in the Background of the Invention he discusses different conditions of evaporation, which affect the crystallization of the compound and its end form.

It would have been obvious for anyone of ordinary skill to vary the conditions of evaporation of solvents in a different way than disclosed by Schuler, namely by using capillaries along with other types of receptacles, because this is another way to find out the best conditions for obtaining crystalline, rather than amorphous, form of the compound, as discussed by Schuler in col. 2, lines 20-35. It would have been obvious for anyone of ordinary skill to subject at least two samples to different conditions of solidifying, which results in different crystalline forms of the compounds, because Schuler directly expressed that the condition of the evaporation strongly affects the result of crystallization.

19. **Claims 6 and 7** are rejected under 35 U.S.C. 103(a) as being unpatentable over Plaas-Link. Plaas-Link does not specifically disclose placing the same sample in a plurality of

capillaries, however, “mere duplication of parts without any new and unexpected results is within the skill in the routineer in the art (see *In re Harza*, 124 USPQ 378 (CCPA 1960)).

20. **Claims 15, 17-19, 44, 46, 48**, are rejected under 35 U.S.C. 103(a) as being unpatentable over Hol in view of Subbiah (US 5,200,910).

Hol does not particularly disclose synchrotron radiation as the radiation source in X-ray analysis and analyzing the sample directly in the capillary.

Subbiah teaches a method for modeling the electron density of a crystal by X-ray analysis of the crystal sample placed in the capillary tube (col. 7, lines 7-12), where X-ray radiation source is a synchrotron (col. 6, line 67).

It would have been obvious for anyone of ordinary skill to use synchrotron as a source of radiation for X-ray analysis and perform the analysis directly in the capillaries, as disclosed by Subbiah, in Hol’s method, because synchrotron is a tunable X-ray source, and because performing X-ray analysis directly in the receptacle where the sample is prepared is convenient and more accurate way of collecting X-ray data.

21. **Claims 16 and 47** are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Hol, Plaas-Link or Schuler in view of Gu et al. (J. Pharmac. Sci., IDS).

Hol, Plaas-Link or Schuler do not teach Raman spectroscopic analysis in their methods or discuss polymorphic forms of the compounds.

Gu teaches characterization of polymorphic forms of the sample using FT Raman spectroscopy.

It would have been obvious for anyone of ordinary skill to use FT Raman scattering analysis instead of X-ray analysis, especially in the case of polymorphic compounds, as taught by Gu, in Hol’s, Plaas-Link’s or Schuler’ method, because as Gu emphasizes, “FT-Raman technique is more suitable for studying certain polymorphs” (Introduction).

22. **Claims 21, 22, 24-33, and 53** are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Hol, Plaas-Link or Schuler in view of Kajola (Acta Chem. Scand., Abstract).

Hol, Plaas-Link or Schuler do not disclose centrifuging the samples in capillaries during crystallization under vacuum.

Kajola discloses “reaction tubes [which] are made by drawing out 10-mm. glass tubing to 2 mm. diam. In these tubes the reagents are mixed and the reaction is carried out in the sealed

Art Unit: 1743

tube. Drawing the end of the reaction tube to a fine capillary produces an effective micro-filter and the mother liquor can be centrifuged through this capillary; any crystals are left in the tube” (Abstract).

It would have been obvious for anyone of ordinary skill to use centrifugation in Hol’s, Plaas-Link’s or Schuler’s process of crystallization of the samples, as taught by Kajola, because Kajola teaches effectiveness of using centrifugation in separating crystal from the solvent in a capillary.

23. **Claims 55 and 56** are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Hol, Plaas-Link or Schuler in view of Kajola, as applied to claims 24-33, and 53 above, and further in view of Bringi et al. (US 4,060,646).

Hol, Plaas-Link or Schuler in view of Kajola does not specifically disclose centrifuging under vacuum.

Bringi teaches fractional crystallization of food fat, wherein “separation of the crystallized fat from the mother liquor may be effected by filtration or centrifugation and accompanied with the application of vacuum or pressure”.

It would have been obvious for anyone of ordinary skill to apply vacuum during centrifugation disclosed by Bringi in Hol, Plaas-Link or Schuler/Kajola’s method, because this increases the effectiveness of the centrifugation.

### ***Response to Arguments***

24. Applicant's arguments filed 10/07/02 have been fully considered but they are not persuasive.

a, ***Rejections under 35 U.S.C. 112, first paragraph.***

The rejection of claim 41 is changed from issue of enablement to the issue of the scope of enablement.

b, ***Rejections under 35 U.S.C. 112, second paragraph.***

The examiner (rather than the Office action itself) explained, why the expression “a method of searching for possible forms of a sample” is unclear and indefinite. “Searching” is not a definite technical term, and it is not clear, what it means in the context of the application. Does

Art Unit: 1743

it have the same meaning as “screening”? The Applicants did not provide any arguments, why such misleading terminology should be used instead of a conventional terminology. It is not clear, why “searching” may include the step of solidifying a sample (i.e. generating different forms of a polymorph), and the term “detecting” or “screening” cannot. The examiner does not suggest a “more suitable language or modes of expression”; rather, she suggests the language that can clear up the subject matter of the invention, as the claims do not meet “the threshold requirements of clarity and precision”. The Applicants are free to be their own lexicographers as long as the claims meet these requirements.

Regarding the expression “forms of the sample”. While the claims should be read in light of the specification, it is not until the middle of the third page of the specification that the reader starts to understand what actually is being claimed, i.e. that the specification discloses the method of generating possible polymorphic forms of compounds and screening for these forms. While specific details of the claims can be enlightened through the specification, the examiner does not believe that the claims should rise the question on what the subject matter of the application is, which is the case with the instant application. The claims are written in a very imprecise, unclear, and indefinite language, which makes them hard to understand. The significant changes in the claims language are required.

The language of claims 26 and 27 stays unclear. The examiner suggested in her question a way to elaborate the meaning of the expression “centrifuging is sufficient to facilitate in-situ analysis” of claim 26; however, no changes were made to the claim. The explanation given in the Applicants’ Remarks regarding this expression should be introduced into the claim, so that the claim can be understood.

The explanation of the language of claim 27 did not make it clearer. The examiner still does not understand, how changing the centrifuging conditions can provide “environment variation”, and what is meant by the latter expression.

The explanation regarding the language of claim 54 has nothing to do with what it recites. The examiner wonders, how any person of ordinary skills in the art would be able to interpret claim 54 the way it is explained in the Remarks: that the centrifuging step should at least partially overlap with the solidifying step. Why this is not expressed in the same plain language in the claim?

Art Unit: 1743

c, *Rejections over the prior art.*

Unclear and indefinite language of the pending claims provides the basis for their free interpretation. All the prior art cited in the previous Office action reads on the claims the way they are written. "The Office action understood" (with some efforts) of what the invention claims; however, the claims the way they are written do not reflect the real essence of the invention. Since "searching for possible forms of a sample" is not a definite expression, it can be interpreted the way the examiner did in the previous Office action, e.g. "searching" for possible crystal forms in order to obtain best of them (Hol and Plaas-Link). The Applicants refer mostly to the aim of the method, rather than its technical means. While Hol's goal is to obtain the best crystals of proteins for X-ray analysis, he uses the same steps of the method that are recited in claims 1-3, 6-9, 11, 13, 14, 20, 21, 34-37, 39, 40, 42, 43, 45 and 50-52. Why "good" and "bad" (for X-ray analysis) crystals are not different forms of the sample, with Hol searching for the good ones? The claims do not disclose any "polymorphic forms", which are generated and "searched for"; therefore, these arguments are not relevant to the subject matter of the mentioned claims. Also, claims do not recite or provide any hint for "preferred technique" for crystallization, or "a difference in crystallization results arising from the use of different techniques for the crystallization". Hol discloses capillary tubes as possible "receptacles" for crystallization, and therefore they are anticipated by Hol. Again, nothing in the claims leads to the conclusion that different receptacles will provide different polymorphic forms of the compound (not the sample!). Therefore, Hol's reference covers the subject matter of the mentioned claims.

Regarding rejection over Plaas-Link. The Applicants refer to "determining crystal forms of a sample". Which exactly claims recite "crystal forms of a sample"? Again, why the attempts to crystallize and get the best crystals cannot be considered "searching for crystal forms" by varying conditions and using capillaries? The argument that the claims require "classifying solids according to form" versus classifying solids as crystals is not quite clear. Then which forms are meant here?

Regarding Shuler's prior art. The same question arises, as where in the claims it is indicated that amorphous forms are desirable? Schuler discloses exactly the same method as the Applicants as it is recited in the claims – he is searching for different solid forms by taking the

Art Unit: 1743

same steps as the Applicants, although with a goal to find the best crystals, rather than amorphous forms. The method disclosed by Shuler anticipates the method claimed by the Applicants, although it may have a different purpose.

Again, the arguments regarding JP 06095190 are not clear, because it is not apparent, what the Applicants mean by “classifying the crystal according to form” (*which form – its form?*), and where in the claims “the classification of **the crystal** according to form” is recited.

The rejections under 35 U.S.C. 103(a):

Over Schuler: Schuler discloses different conditions affecting crystallization, including the rate of evaporation; he also discloses capillaries as good receptacles for crystallization, especially since it is known, that the rate of evaporation is slow in capillaries. It is not clear, why it wouldn't have been obvious for anyone of ordinary skills in the art to use different receptacles for obtaining the best crystals, when it is known, that different types of receptacles define the conditions of evaporation, which affect crystallization process?

Over Plaas-Link: the claims do not indicate the unexpected result from using more than one capillary for the same sample. They do not recite generating more possible polymorphic forms of the compound upon placing the sample in a plurality of the capillaries, and therefore the rejection stands as it was established previously.

Over Hol in view of Subbiah: the arguments are not persuasive, as no arguments overcame rejections over the primary reference.

Over Hol, Plaas-Link or Schuler in view of Gu: no polymorphic compounds are recited in the claims, and the claims do not even remotely recite methods, which “provide a way to find out if a sample is a polymorphic compound”. Therefore, these arguments are not relevant to the subject matter of the claims.

Over Hol, Plaas-Link or Schuler in view of Kajola: the same statement is applicable which was made for Hol in view of Subbiah.

Over Hol, Plaas-Link or Schuler in view of Kajola and Bright: The arguments are not relevant to the subject matter of the claims. The claims do not recite any relation between crystallization and centrifugation. Performing centrifugation under vacuum is a routine procedure, and Bright is just one example of it.

Art Unit: 1743

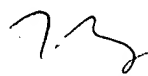
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (703) 306-5906. The examiner can normally be reached on 10:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-7165 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

YG

November 28, 2002

  
T. TUNG  
PRIMARY PATENT EXAMINER  
ART 1743